OneLab 1.16
Operational Qualification Procedure

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1. Operational Qualification (OQ)

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The **Operational Qualification (OQ)** is a test process that evaluates the proper functioning of a facility or an appliance. The Operational Qualification (OQ) may only be performed after a successfully completed Installation Qualification (IQ). The documentation for an Operational Qualification consists of:

- OQ test plan
- OQ report

1.1. OQ test plan

The **OQ test plan** contains detailed information of the tests to be performed on the respective equipment in the context of the Operation Qualification (OQ). This test plan contains detailed specifications on the course of the test itself.
After completion of the OQ test plan, the results are summarized, evaluated, and combined in an OQ report. All deviations, as well as measures taken to eliminate these, are documented. After the deviations have been eliminated, they must be tested again, documented, and evaluated in a new OQ report.
The Operational Qualification template for OneLab is reported in the next page.

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1.2. Getting started

This Operational Qualification procedure is based on the execution of a set of workflows to test the correct functionality of different features of the system.
In case of an enterprise deployment, Installation Qualification must be successfully performed before starting the Operation Qualification procedure.

A) SaaS / Minor release OQ Process

In case of an OQ Process on the SaaS environment or being done for a minor release, only the Workflow 3 could be executed.
In this case, requirements would be to log in with a user having one of the roles listed in the related requirements- this could be a user created in an earlier qualification workflow, one of your own configured users, or, when using an outside expert to run qualification, a user account / accounts configured specifically for this individual. All used users should be in the same lab.

B) Enterprise OQ Process

a. Requirements: about initial configuration

- The OQ performer must be allowed to access the platform administration of OneLab
- The OQ Platform administrator user must have been created or enabled (if user already existed) by an effective platform administrator and credentials must have been communicated to the OQ performer

OQ platform administrator work email:
OQ platform administrator password:

- OQ Platform administrator user must be disabled by a “real” platform administrator after the OQ Process has been performed

b. Requirements: about configuration variables

Following settings are set during the IQ Process and should be communicated to the OQ performer so that workflows can be executed properly.

- OneLab URL

- Account creation: restriction to a domain list

allowed:	**blocked:**

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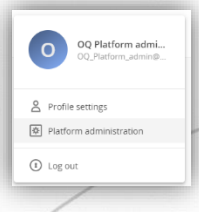
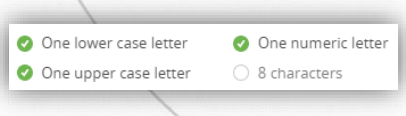
- Password policy

☐ **Workflows are based on default password policy**	☐ **Password policy has been customized:**
○ One lower case letter ○ One numeric letter ○ One upper case letter ○ 8 characters	

1.3. Workflow 1: Platform administration

Requirements: • **Platform installed with a license added**		
Tested features: • *Platform administration: user creation* • *Platform administration: lab creation* • *Platform administration: lab members management* • *Password policy control* • *Audit trail with a reason*		
Go to OneLab URL **Log in using OQ Platform administrator credentials**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on the user's avatar in the top right corner **Click on the Platform administration link**  **Platform administration dashboard is displayed**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on "Users" link in the left menu **Click on the "Add new user" button** • **Fill "Full name" field with "*OQ Lab admin (YYYYMMDD)*"** • **Fill "Work email" field with a valid and allowed email** • **Fill "Password" field with "*Test_User_1234*"** • **Click on "Add new user" to submit the form**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Created user is listed in the Users table	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on the "Add new user" button • **Fill "Full name" field with "*OQ Expert user (YYYYMMDD)*"** • **Fill "Work email" with a valid and allowed email**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Check that password policy conditions are instantaneously updated by filling "Password" field with "*a1A23456*" 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on "Add new user" to submit the form **Created user is listed in the Users table**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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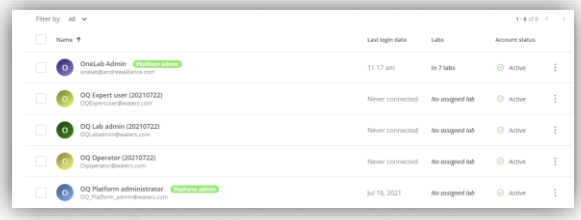
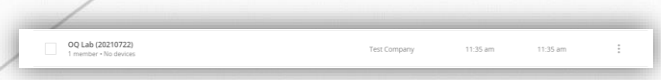
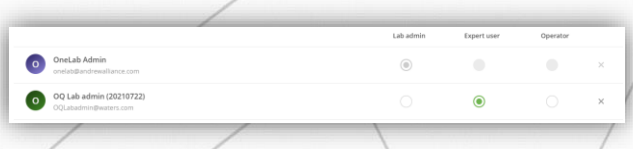
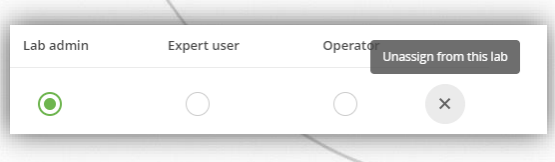
Click on the "Add new user" button • **Fill "Full name" field with "*OQ Operator (YYYYMMDD)*"** • **Fill "Work email" with a valid and allowed email** • **Fill "Password" field with "*Test_User_4321*"** • **Click on "Add new user" to submit the form**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Created users are listed in the Users table 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on "Labs" link in the left menu **Click on the "Create new lab" button** • **Fill "Lab name" field with "*OQ Lab (YYYYMMDD)*"** • **Fill "Company or division name" field with "*Test Company*"** • **Click on "Create new lab" to submit the form**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Created lab is listed in the Labs table 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on the created lab line **Check that OQ Platform administrator user is the Lab admin**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on the "Add users" button at the bottom of the page **In the popup, select " OQ Lab admin (YYYYMMDD)" and submit by clicking on "Add 1 user" button**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
User is added and automatically designated as an expert user 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Check that OQ Platform administrator lab admin's role cannot be changed (buttons cannot be clicked)	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Change " OQ Lab admin (YYYYMMDD)" role to Lab admin	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Check that OQ Platform administrator role can now be changed (buttons can now be clicked)	OK ☐ NOK ☐	Comment (if none, check this checkbox ☐)
Unassign him from the lab by clicking on the cross at the end of the line 	OK ☐ NOK ☐	Comment (if none, check this checkbox ☐)

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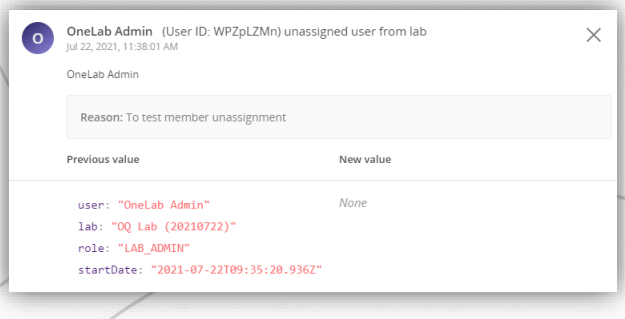
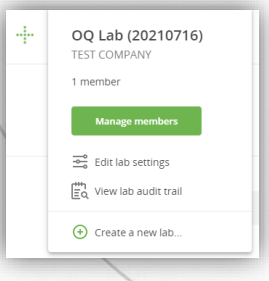
A confirmation popup is displayed, and a reason must be entered to unassign the user from the lab		
Enter "To test member unassignment" in the reason field and submit	OK ☐ NOK ☐	Comment (if none, check this checkbox ☐)
Click on "platform audit trail" link in the left menu	OK ☐ NOK ☐	Comment (if none, check this checkbox ☐)
A line related to the previous unassignment must be displayed	OK ☐ NOK ☐	Comment (if none, check this checkbox ☐)
Click on the line **Check that the reason entered before is correctly displayed** 	OK ☐ NOK ☐	Comment (if none, check this checkbox ☐)

1.4. Workflow 2: Lab management & permissions

Requirements: • **Workflow 1 has been validated**		☐
Tested features: • *Lab management: invite a user* • *Lab management: members role administration* • *An expert user can design a protocol* • *An operator cannot design a protocol*		
Go to OneLab URL • **Work email: email entered for user *OQ Lab admin (YYYYMMDD)* in Workflow 1** • **Password: "*Test_User_1234*"**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Check in the top left corner that user is automatically logged in lab "*OQ Lab (YYYYMMDD)*"	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on the lab menu **Click on "Manage members"**  **Then, click on "Invite new member"**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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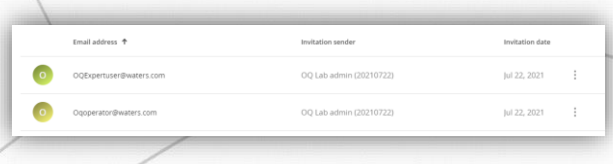
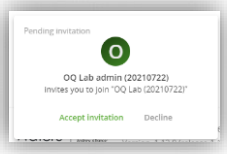
In the "Work mail" field, enter email used for "*OQ Expert user (YYYYMMDD)*" **Check that the role is automatically set to "Expert user"** **Submit by clicking on "Send invitation"**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on "Invite new member" button again **In the "Work mail" field, enter email used for "*OQ Operator (YYYYMMDD)*"** **Check that the role is automatically set to "Expert user"**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Change the role to "Operator" **Submit by clicking on "Send invitation"**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
A green feedback is displayed to confirm that the invitation has been sent	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Check that members table is automatically displaying the "Invites" tab instead of the "Active" tab	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Check that both invited users are listed 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Log out from OneLab **Log in OneLab with "OQ Expert user" credentials** • **Work email: email entered for "*OQ* Expert user *(YYYYMMDD)*"** • **Password: "*a1A23456*"**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Depending on the lab creation policy: **If "*none*":** • **A welcome to OneLab screen is displayed** • **A message displays that user does not have access to any labs** **If "*many*" or "*one*":** • **A welcome to OneLab screen is displayed** • **A name must be given to the user's lab and is prefilled with "OQ Expert user (YYYYMMDD)'s Lab"** • **Select one of the applications displayed** • **Click on "Go to OneLab!" button in the top right corner** • **User is directed to the homepage of OQ Expert user (YYYYMMDD)'s lab**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
In the bottom left corner, an invitation card from OQ Lab admin to join OQ Lab is displayed 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on "*Accept invitation*" **A green feedback is displayed**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Depending on the lab creation policy: **If "*none*":** • **Check in the top left corner that user is now in "*OQ Lab (YYYYMMDD)*"**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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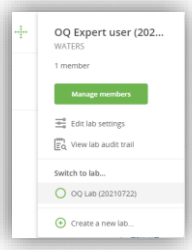
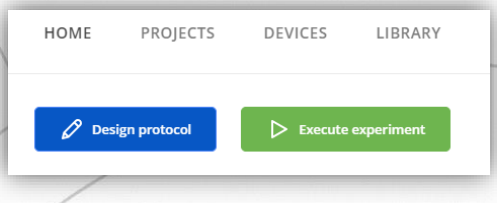
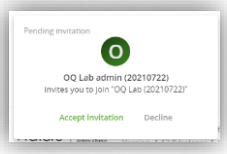
If "*many*" or "*one*": • **Click on the lab menu** • **Click on "OQ Lab (YYYYMMDD)" in the "switch to lab…" section**  • **Check in the top left corner that user is now in "*OQ Lab (YYYYMMDD)*"**		
Check that the "Design protocol" button can be clicked 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Log out from OneLab **Log in OneLab with "OQ Operator" credentials** • **Work email: email entered for "*OQ* Operator *(YYYYMMDD)*"** • **Password: "*Test_User_4321*"**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Depending on the lab creation policy: **If "*none*":** • **A welcome to OneLab screen is displayed** • **A message displays that user does not have access to any labs** **If "*many*" or "*one*":** • **A welcome to OneLab screen is displayed** • **A name must be given to the user's lab and is prefilled with "OQ Expert user (YYYYMMDD)'s Lab"** • **Select one of the applications displayed** • **Click on "Go to OneLab!" button in the top right corner** • **User is directed to the homepage of OQ Operator (YYYYMMDD)'s lab**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
In the bottom left corner, an invitation card from OQ Lab admin to join OQ Lab is displayed 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on "*Accept invitation*" **A green feedback is displayed**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Depending on the lab creation policy: **If "*none*":** • **Check in the top left corner that user is now in "*OQ Lab (YYYYMMDD)*"**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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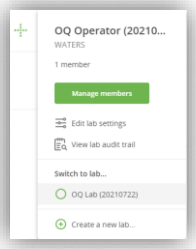
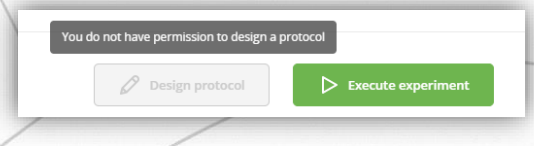
If "*many*" or "*one*": • **Click on the lab menu** • **Click on "OQ Lab (YYYYMMDD)" in the "switch to lab…" section**  • **Check in the top left corner that user is now in "*OQ Lab (YYYYMMDD)*"**		
Check that the "Design protocol" button is disabled 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Log out from OneLab	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

1.5. Workflow 3: Design & Execute (SaaS / Minor release OQ Process)

Requirements:
- **Full OQ Process: Workflow 2 has been validated**
- **SaaS / Minor release OQ Process:**
  - **For each workflow, log in with a user having one of the roles listed in the related requirements- this could be a user created in an earlier qualification workflow, one of your own configured users, or, when using an outside expert to run qualification, a user account / accounts configured specifically for this individual**
  - **All used users should be in the same lab**

A) Design a protocol

Requirements: • **SaaS / Minor release OQ Process: Log in with a user being a lab admin or an expert user**		☐
Tested features: • *Create a project* • *Import a protocol* • *Design a protocol* • *Import reagents from a data table into a labware*		
Go to OneLab URL • **Work email: email entered for "*OQ Expert user (YYYYMMDD)*"** • **Password: Test_User_1234**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Check in the top left corner that user is in "*OQ Lab (YYYYMMDD)*"	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on "PROJECTS" tab at the top center of the screen **Click on the card "New project"** **The form to create a new project is displayed**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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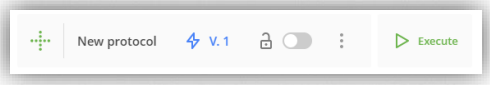
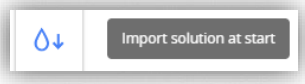
Fill "Project name" field with "*OQ Project (YYYYMMDD)*" **Let the "Description" field empty** **Select a project color** **Check that "Initials" field is automatically filled with "*OQ*"** **Click on "Create project" button**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
A green feedback is displayed to confirm project creation **The new created project is automatically opened** **The selected color is correct, and initials are OQ**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on the link "*Import protocol file (.onp)…*" **Select the dedicated OQ protocol furnished with the OQ process**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
A green feedback is displayed to confirm the successful import	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
The protocol is listed in the project	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on the "Design new" button 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
The designer opens on a New protocol **The version of the protocol is V.1** 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
An onboarding message asking to "*add a labware to the bench*" is displayed	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on the protocol name **Protocol information screen is displayed**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Change protocol title to "OQ protocol (YYYYMMDD)" **Click on update button**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Bench is displayed again **Protocol title has been correctly updated**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click the "*Import solution at start*" icon in the toolbar  **The dedicated screen is displayed**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Copy the dedicated sheet "OQ Import Solution (Workflow3)" to your clipboard (ctrl+c)	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Paste from clipboard using the dedicated button	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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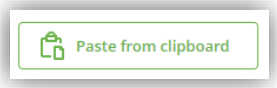
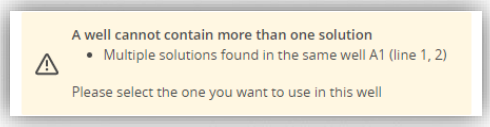
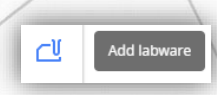
		
A warning message is displayed "*A well cannot contain more than one solution*" 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click the first checkbox for A1 position **Check that related warning message is no more displayed**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click the "Select your labware" button	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Check that only 384 microplates can be selected in the catalog (filter should be automatically applied on 384 number of wells)	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Select "*Greiner, 384-well standard microplate*" by clicking on the dedicated button	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on "*Create and fill labware*" button **Bench with the microplate is displayed again, filled with solutions previously imported** 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on the "*Add labware*" icon in the toolbar 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
In the well capacity filter, click on "*50 mL - 250 mL*"	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Check that only related labware are displayed	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Select "Falcon 50mL conical centrifuge tube" by clicking the "Add" button	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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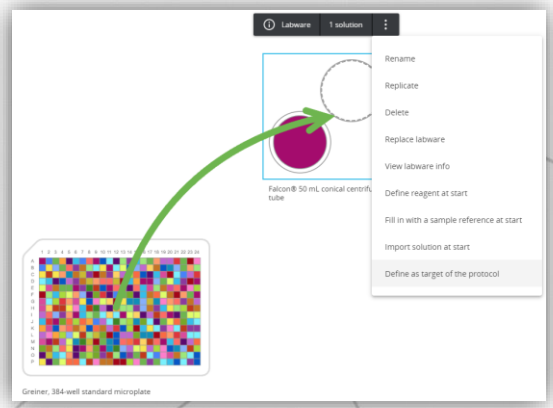
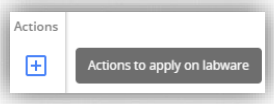
Click the "*Add to bench*" button	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Back on the bench, click on the microplate and drag the cursor to the 50mL tube	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
On the screen dedicated to select sources, click on A1 and B1 **Click on Save selection**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
In the volume field, enter 10 and check that the button to "*Save*" **the step turns from disabled to enabled** **Click on Save step**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Back to the bench, the created step is listed, and an arrow is displayed from the microplate to the tube	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on the tube **In the labware menu, click on the three dots then on "*Define as target of the protocol*"** 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
On the bench, the tube should have a "*Target*" label	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on the "*Actions*" icon in the toolbar 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click the Heat/cool action icon	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on the microplate and drag it to the dedicated zone "*Labware to heat*"	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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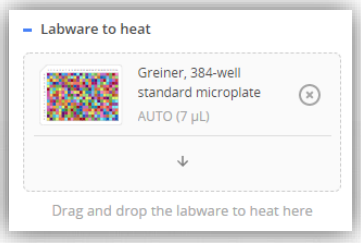
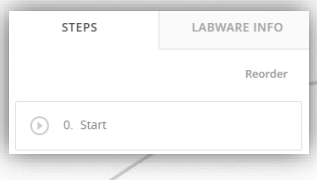
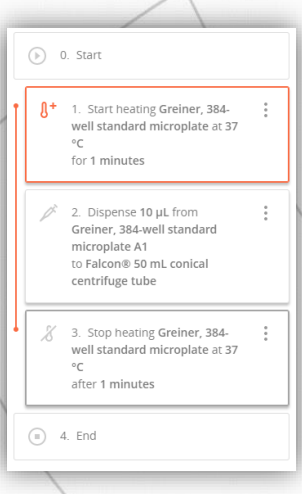
		
Select the temperature of 37 °C	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Check that the advanced option to place the labware only once the device reached the desired temperature is checked 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Check that the advanced option to remove the labware from the device once the protocol has been done is checked	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Save the step **Back to the bench, the "Heat/cool" icon should be displayed above the microplate and should be orange**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Above the steps list, click the Reorder button 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Drag the Start heating step from position 2 to position 1, so that the pipetting gets in between the start and the stop 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Above the steps list, click the Done button	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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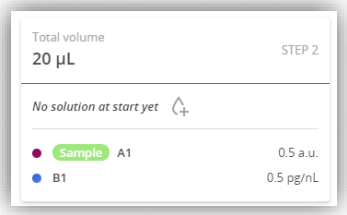
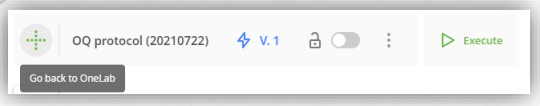
Click the pipetting step (position 2) **Click the tube on the bench** **In the labware menu, check that "*2 solutions*" is displayed**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on "*2 solutions*" **Check that A1 well is flagged as a sample** **Check that B1 is not flagged as a sample** 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on the "*Execute button*"	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
The setup page should display a line dedicated to a Manual execution **An estimation time should be displayed**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on cancel and check that the designer is displayed again	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click the OneLab icon to exit the designer 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
The protocols list of "*OQ Project (YYYYMMDD)*" is displayed	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Log out from OneLab	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

B) Execute a protocol

Requirements: • **SaaS / Minor release OQ Process: Log in with a user being an operator, or an expert user or a lab admin**		☐
Tested features: • *Execute a protocol: bar code scanning for labware & samples* • *Execute a protocol: manual execution* • *Experiment report: electronic signature* • *Experiment report: release & sign a report*		
Log in OneLab with "OQ Operator" credentials • **Work email: email entered for "*OQ* Operator *(YYYYMMDD)*"** • **Password: "*Test_User_4321*"**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
The "*OQ Project (YYYYMMDD)*" card is displayed in the Quick access area	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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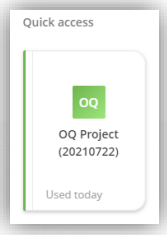
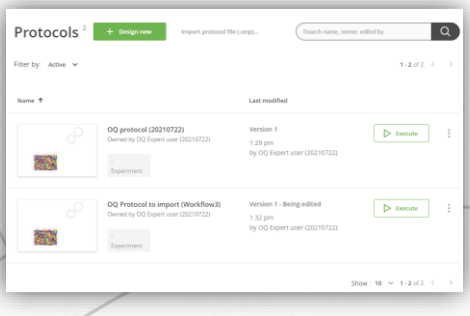
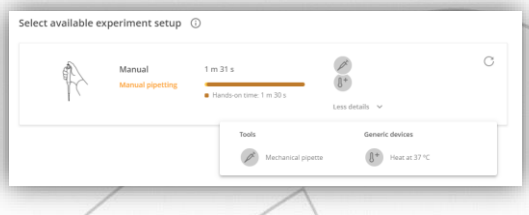
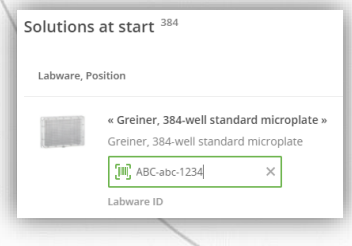
 **Click the card**		
The protocols list is displayed **The previously imported protocol is listed** 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on the Execute button of the previously imported protocol	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
The setup page should display a line dedicated to a Manual execution	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
An estimation time should be displayed  **Click on the line**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
The Material list screen is displayed **Check that a generic device to heat at 37°C is requested**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Scroll down to find the "*Solutions at start*" section, and click on the button Labware ID	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
If a bar code reader is available, scan a bar code in the field **If no bar code reader is available, enter "*ABC-abc-1234*" in the field** 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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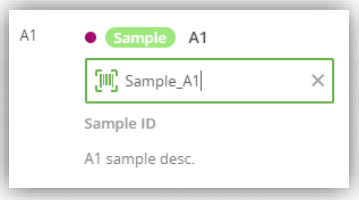
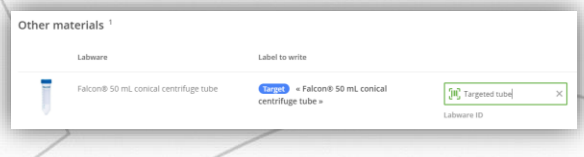
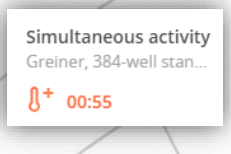
Check that a Sample ID button is available for all wells on the A line and enter "*Sample_A1*" in A1 field 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Check that no "*sample ID*" button is available for all wells on the B line	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Scroll down to find the "*Other materials*" section, and click on the button Labware ID of the targeted tube **Enter "*Targeted tube*" in the field** 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Scroll up to the top of the material list and click the Start experiment button	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
First step of the execution asks to check that the heating device is at 37°C **Click on the next step button**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
A start button is available to start the timer **Click on the start button**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
The heating timer is displayed on a dedicated card, in the "*simultaneous activity*" section of the runner 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
During the heating, the pipetting step from A1, B1 to the tube is displayed **A sample tag is displayed under the microplate** **Click on the continue button**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Wait until the "end of heating" step is displayed **Once timer is finished, continue button switches from disabled to enabled** **Click on the continue button**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Last step asks the user to remove the microplate from the device **Click on "*End experiment*" button**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Experiment report is displayed	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Scroll down to the Target labware section **Check that Labware ID is "*Targeted tube*"** **Check that Sample ID is "*Sample_A1*"**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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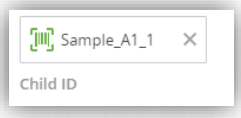
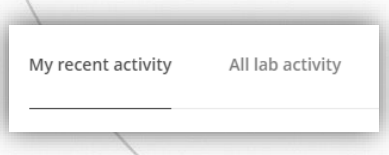
Click the "*Autofill all of child IDs*" button **Check that Sample_A1 child ID is automatically filled, and its value is "Sample_A1_1"** 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Check that the "*Export sample information*" button is not available **Check that the "*Print*" button at the top of the screen is not available**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click the "*Release report*" button at the top of the screen **In the reason field, enter "To test *Report releasing*"** **In the credential fields, enter:** • **Work email: email entered for "*OQ Operator (YYYYMMDD)*"** • **Password: Test_User_4321** **Click the "*Sign experiment* report" button**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Check that the report is correctly released and signed by "*OQ Operator (YYYYMMDD)*" 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Check that the Print button at the top of the screen is now available **Check that the Export sample information is now available** **Click on "*Go to OneLab home*"**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Log out from OneLab	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

C) Review and archive a protocol

Requirements: • **SaaS / Minor release OQ Process: Log in with a user being a lab admin**		☐
Tested features: • *Experiment report: review a report* • *Archive a protocol*		
Log in OneLab with "OQ Lab admin" credentials • **Work email: email entered for "*OQ* Lab admin *(YYYYMMDD)*"** • **Password: "*Test_User_1234*"**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
On the homepage, click the "All lab activity" link 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
A line dedicated to the previous experiment report release is displayed	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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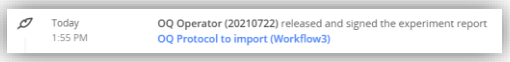
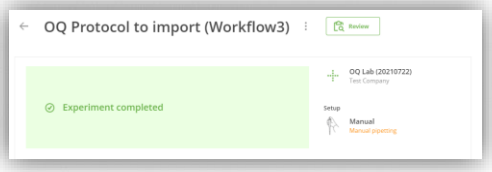
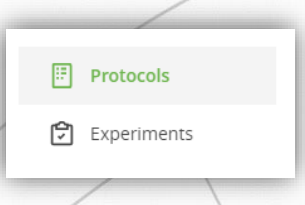
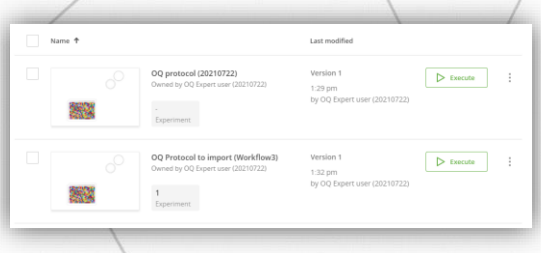
 **Click on the experiment report link on this line**		
The experiment report is displayed, and a "review" button is available 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click the "*Review*" button at the top of the screen **In the reason field, enter "To test *Report reviewing*"** **In the credential fields, enter:** • **Work email: email entered for "*OQ Lab admin (YYYYMMDD)*"** • **Password: Test_User_1234** **Click the "*Review experiment report*" button**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Check that the report is correctly reviewed by "*OQ Lab admin (YYYYMMDD)*" 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on the Protocols link on the left of the screen 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
The protocols list is displayed **The previously imported protocol is listed** 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
In the protocols list, click on the three dots at the end of the line related to the protocol "OQ Protocol to import (Workflow3)"	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click the Archive button	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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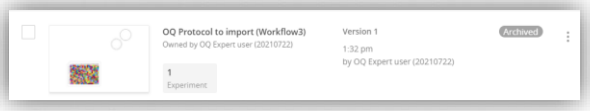
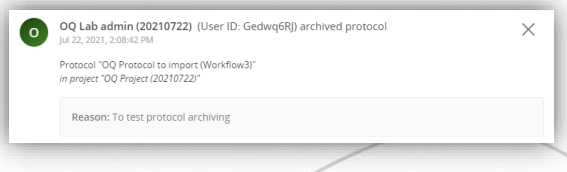
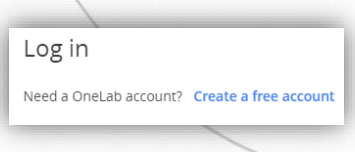
In the dedicated pop up, enter the reason "To t*est protocol archiving*"	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Check that the protocol is no longer listed in the protocols list, under the "filter by: Active" which is selected by default	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Change the filter value to select "*Archived*" and check that "OQ Protocol to import (Workflow3)*" is listed with an archived tag and that it cannot be executed anymore* 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click the lab menu in the top left corner	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click the " *View lab audit trail* entry	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
A line related to the previous experiment report review must be displayed	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
A line related to the previous protocol archived must be displayed Click on the line	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Check that the reason entered before is correctly displayed 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Log out from OneLab	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

1.6. Workflow 4 (optional): Signup & email

Requirements: • **Signup is activated (cf. Installation guide)** • **Emails are activated, either via smtp or logs (cf. Installation guide)**		☐
Tested features: • *Create an account* • *Emails*		
Go to OneLab URL	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on the link "*Create a free account*" 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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Fill "Full name" field with "*OQ New User (YYYYMMDD)*" **Fill "Work email" field with a valid and allowed email** **Fill "Password" field with "*Test_User_0*"** **Click the continue button**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
A screen asking to check your email is displayed 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Check that the email has correctly been received	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
In the email, click the link to activate the account	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
The login page of OneLab opens	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
The work email field is automatically filled with the email entered during the account creation	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Fill the "Password" field with "Test_User_0" **Click on the Login button**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Depending on the lab creation policy: **If "*none*":** • **A welcome to OneLab screen is displayed** • **A message displays that user does not have access to any labs** **If "*many*" or "*one*":** • **A welcome to OneLab screen is displayed** • **A name must be given to the user's lab and is prefilled with "OQ new User (YYYYMMDD)'s Lab"** • **Select one of the applications displayed** • **Click on "Go to OneLab!" button in the top right corner** • **User is directed on the homepage of OQ New User (YYYYMMDD)'s lab**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

1.7. Workflow 5: Reset

Requirements: • **This workflow is dedicated to purge the data that have been created during this OQ process. Therefore, it should be used applied to all records created during the OQ execution.**		☐
Tested features: • *Platform administration: archive a lab* • *Platform administration: disable a user*		
Go to OneLab URL **Log in using OQ Platform administrator credentials**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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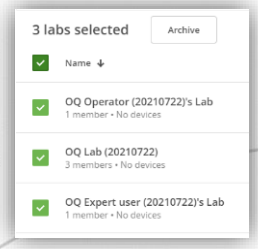
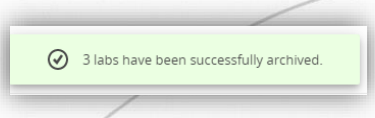
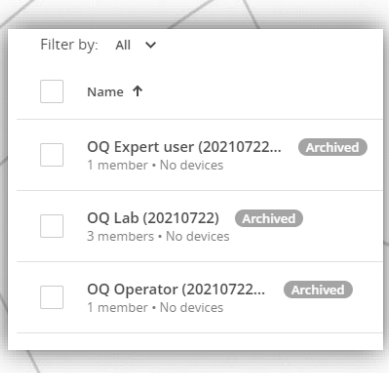
Click on the user's avatar in the top right corner **Click on the Platform administration link** **Platform administration dashboard is displayed**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on "*Labs*" link in the left menu	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Use the search field to filter results on YYYYMMDD **All labs created during this OQ process should be listed**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click the select all checkbox **An archive button is displayed** 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click the archive button **A confirmation pop up is displayed and a reason must be entered to unassign the user from the lab**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Enter a "To t*est lab archiving*" and submit	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
A green feedback indicates that the lab is now archived 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Check that the labs are tagged as archived 	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on "users" link in the left menu	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Check all the checkboxes for all users created during this OQ process: • **OQ Lab admin (YYYYMMDD)** • **OQ Expert user (YYYYMMDD)**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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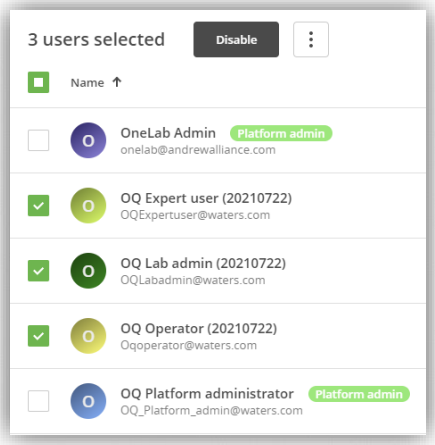
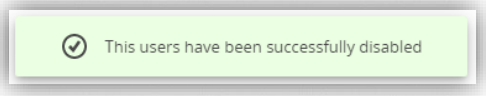
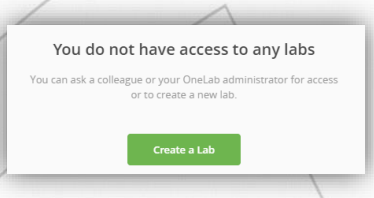
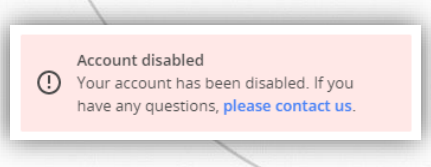
• **OQ Operator (YYYYMMDD)** • **OQ New User (YYYYMMDD) [if workflow 4 was done]**		
Click the "Disable" button  **A confirmation pop up is displayed and a reason must be entered to unassign the user from the lab**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Enter "To *test users deactivation*" and submit	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
A green feedback indicates that the users are now disabled  **Account status for these users is "Disabled"**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Quit the platform administration by clicking on the arrow on the top left of the screen	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
A message indicates that user does not have access to any labs  	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
Click on the user's avatar in the top right corner **Log out from OneLab**	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*
On login screen, try to log in with the email and password that were set for "*OQ Lab admin (YYYYMMDD)*" **An error message indicates that account has been disabled**  	OK ☐ NOK ☐	Comment *(if none, check this checkbox ☐)*

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1.8. OQ test report

Below Operation Qualification Report is shown. The Operation Qualification is successful if all executed workflows passed **ALL** the tests.

OPERATION QUALIFICATION REPORT		
OQ test	***RESULT***	***COMMENT (if none, bar the cell)***
WORKFLOW 1	OK ☐ NOK ☐	
WORKFLOW 2	OK ☐ NOK ☐	
WORKFLOW 3	OK ☐ NOK ☐	
WORKFLOW 4	OK ☐ NOK ☐ NOT APPLICABLE ☐	
WORKFLOW 5	OK ☐ NOK ☐	
Reminder	As specified in Requirements: **OQ Platform administrator user must be disabled by an effective platform administrator after the OQ Process has been performed** OK ☐ NOK ☐	

	Function	**Name**	**Date**	**Signature**
Performed by				
Approved by				

2. Contact

For any questions or information, do not hesitate to:

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